APR 18 2014

510(k) Summary

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

Submitted by: Biomet Trauma
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Contact Person: Victoria Scheitlin, Regulatory Affairs Specialist

Date Prepared: March 2014

Proprietary Name: OrthoSorb LS

Common Name: Pin, Fixation, Reabsorbable, Hard Tissue

Classification Name / Product Code: Smooth or threaded metallic bone fixation fastener. (21 CFR § 888.3040) / OVZ

Predicate Devices: Biomet's OrthoSorb LS is substantially equivalent to the currently marketed devices: Depuy's Orthosorb Resorbable Pins (K901456 and K111077), and Biomet's LactoSorb Bone Pin (K990291).

Device Description: Biomet OrthoSorb LS resorbable fixation devices include straight and tapered pins. Biomet OrthoSorb LS resorbable fixation devices are made of a resorbable copolymer, polyester derivative of L-lactic and glycolic acids. Poly L-lactic/polyglycolic acid copolymer degrades and resorbs *in-vivo* by hydrolysis into L-lactic and glycolic acids which are then metabolized by the body.

Indications for Use: 1.) To fix in place small bony or chondral fragments in the knee and hand where such fragments are not in tension, as in the case of osteochondritis dissecans or fractures of the phalanges and metacarpals;
2.) For fixation of inherently stable osteotomies of the great toe and first metatarsal and intramedullary stabilization of

joint arthroplasty (resection) for the treatment of lesser toe deformities.

3.) Used to provide additional support in cases of finger joint fusion and digit replantation where standard fixation or support techniques are also employed.

Technological Characteristics:

The technological characteristics of OrthoSorb LS are similar to currently marketed devices including design, dimensions, and material.

Summary of Substantial Equivalence:

OrthoSorb LS is substantially equivalent to currently marketed devices demonstrated through mechanical testing that was performed to ASTM D6272, which highlights the method for flexural properties, specifically testing protocol four-point bending. Single Shear testing was also performed which represents a common loading condition observed *in-vivo* during which the bone pin is used to fix bony fragments No new issues of safety or efficacy have been raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 18, 2014

Biomet Trauma
Ms. Victoria Scheitlin
Regulatory Specialist
56 East Bell Drive
Warsaw, Indiana 46581

Re: K140625
Trade/Device Name: OrthoSorb LS
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: OVZ
Dated: March 7, 2014
Received: March 11, 2014

Dear Ms. Scheitlin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K140625

Device Name: OrthoSorb LS

Indications For Use:

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Prescription Use X AND/OR Over-the-Counter _____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices